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PSRO — AN ALTERNATIVE TO THE MEDICAL MALPRACTICE SYSTEM AS A QUALITY ASSURANCE MECHANISM

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With the passage of the Social Security Admendments of 1972,¹ Congress established the Professional Standards Review Organizations (PSROs) "to promote the effective, efficient, and economical delivery of health care services of proper quality"² for which health care providers are reimbursed under federal programs. PSROs are local organizations of practicing physicians that will attempt to determine whether the health care services provided to the beneficiaries of Medicare, Medicaid, and Maternal and Child Health programs "conform to appropriate professional standards."³ These organizations will review medical services to determine whether they are medically necessary, whether the quality of care meets professionally recognized standards, and, in the case of services provided in an inpatient facility, whether the choice of facility is appropriate. The PSRO review incorporates various features of previous systems of peer review.

PSROs evaluate medical necessity and appropriateness of care by means of a complex procedure. Initially, a local physician organization develops the review criteria for local medical care. Screening, the first level of review, is performed by nonphysicians who apply the predetermined criteria to an individual medical record. If information in the record indicates that the criteria have not been satisfied, then the record receives a second level of review conducted by a peer (physician) in which individual patient variation may be considered. In this manner, the bulk of the records can be screened rapidly, and physician time can be limited to those cases requiring greater knowledge and experience. Upon completion of the review process, the PSRO recommends to the government whether the reviewed health care services should be reimbursed.

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The views expressed herein are solely those of the author and do not necessarily represent those of the Department of Health, Education, and Welfare or any of its components.

1. 42 U.S.C. §§ 1320c-1 to -19 (1974).

2. 42 U.S.C. § 1320c (1974). *See also* S. REP. NO. 1230, 92d Cong., 2d Sess. 261 (1972) [hereinafter cited as S. REP. NO. 1230].

3. 42 U.S.C. § 1320c (1974). The congressional premise was that "only physicians are, in general, qualified to judge whether services ordered by other physicians are necessary." S. REP. NO. 1230, *supra* note 2, at 256.

The PSRO system also includes programs that constantly review the criteria themselves and identify and correct deficiencies in health care delivery.

Because PSRO represents the federal government's most structured attempt to control the quality of health care, and because the program has begun operation in the midst of a malpractice "crisis,"⁴ it is not surprising that PSROs have been discussed in the context of the malpractice system.⁵ Since malpractice litigation serves diverse functions, although none of them very well, any proposed alternative to malpractice litigation must fulfill those same functions. This article will analyze some of the important concepts of various quality assurance mechanisms and describe the workings of the PSRO system. It is hoped that PSRO will obviate the need for malpractice litigation to serve as a principal source of quality assurance. This change may enhance the attractiveness of alternatives to the malpractice system that address themselves to other facets of the problem such as injury compensation.⁶

I. QUALITY ASSURANCE IN MEDICAL CARE

A. *An Overview*

Concern over the quality of medical care is not new. Hippocrates in the Physician's Oath recognized the physician's potential to do both harm and good: "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrongdoing."⁷ For centuries, physicians have attempted to assure the good quality of their practice. For example, tissue review, which involves the examination of surgically removed specimens, is a routine procedure in most hospitals. Medical records committees, which provide informal review of selective patient records, are another means to assure the quality of medical practice. There are also numerous hospital conferences at which bad patient results are scrutinized.

A major deficiency of many past and present quality assurance programs, however, is that they have lacked organization and failed to develop an adequate framework for appraisal. Too often the programs consisted of random, retrospective reviews of individual cases, conducted without the guidance of recognized standards.⁸ The care received by a particular

4. The "crisis" is not technically one of malpractice, but of costs, manifested primarily in the relative unavailability of professional liability insurance.

5. See, e.g., Springer, *PSROs: Implications for Legal Liability*. THE HOSPITAL MEDICAL STAFF 1 (January 1975); Note, *PSRO: Malpractice Liability and the Impact of the Civil Immunity Clause*, 62 GEO. L.J. 1499 (1974); Editorial, *PSRO and Malpractice*, J. LEGAL MED. 6 (Sept.-Oct. 1974).

6. See, e.g., O'Connell, *An Alternative to Abandoning Tort Liability: Elective No-Fault Insurance for Many Kinds of Injuries*, 60 MINN. L. REV. 501 (1976).

7. See also Gordis, *An Early Commentary on Medical Care*, 292 NEW ENGLAND J. MED. 44-45 (1975).

8. See A GUIDE TO MEDICAL CARE ADMINISTRATION, VOLUME II: MEDICAL CARE APPRAISAL — QUALITY AND UTILIZATION 27 (A. Donabedian ed. 1969) [hereinafter

patient was examined, but it was not usually compared with objective or predetermined standards.

The concept of designing quality assurance mechanisms that include standards for measurement and a means by which to evaluate the results of applying the standards is relatively new. The reasons for this delay can be traced to the development of medical care itself. Less than a century ago, patient care was primarily an interaction between only two people — the patient and his physician. Since the practice of medicine was less scientific, assurance of quality depended on the physician's knowledge, skill, and his Hippocratic "judgment." As medical knowledge expanded, the responsibility for patient care extended to a larger number of people who performed loosely defined roles. Only recently have quality assurance mechanisms considered this shift in the practice of medicine.⁹ Individual physician judgment has continued to be the dominant factor in quality control. In order for quality assurance to be effective and measurable, physician judgment must be supplemented by a consistent structure of review that employs appropriate standards of practice.¹⁰

Any system that attempts to assure the quality of medical care must be able to evaluate the quality of care provided. Although there were several earlier efforts at formulating a structured approach to assessing medical care quality, the most significant progress in the development of methods occurred during the last quarter century.¹¹ Paul Lembcke has divided the

cited as Donabedian]; Beaumont, Feigal, Magraw, DeFoe & Carey, *Medical Auditing in a Comprehensive Clinic Program*, 42 J. MED. EDUC. 359 (1967); Zimmer, *An Evaluation of Observer Variability in a Hospital Bed Utilization Study*, 5 MED. CARE 221 (1967).

9. Lembcke, *A Scientific Method for Medical Auditing* (Part I), 33 HOSPITALS 65 (June 16, 1959) [hereinafter cited as Lembcke].

10. See R. BROOK, *QUALITY OF CARE ASSESSMENT: A COMPARISON OF FIVE METHODS OF PEER REVIEW* 59 (1973); Donabedian, *supra* note 8, at 5-7; P. ELLWOOD, P. O'DONOGHUE, W. MCCLURE, R. HOLLEY, R. CARLSON & E. HOAGBERG [INTER-STUDY], *ASSURING THE QUALITY OF HEALTH CARE* 4-5 (1973) [hereinafter cited as INTER STUDY]; Donabedian, *Promoting Quality Through Evaluating the Process of Patient Care*, 6 MED. CARE 181 (1968); Eisele, Slee & Hoffmann, *Can the Practice of Internal Medicine be Evaluated?*, 44 ANNALS OF INTERNAL MED. 144 (1956); Lembcke, *Medical Auditing by Scientific Methods*, 162 J.A.M.A. 646 (1956); McKillop, *Assessing Quality of Medical Care*, 19 HOSPITAL ADMINISTRATION 20 (Fall, 1974); Morehead, *The Medical Audit as an Operational Tool*, 57 AM. J. PUB. HEALTH 1643 (1967); Payne, *Continued Evolution of a System of Medical Care Appraisal*, 201 J.A.M.A. 536 (1967); Williamson, *Evaluating Quality of Patient Care: A Strategy Relating Outcome and Process Assessment*, 218 J.A.M.A. 564 (1971).

11. Although it has received wide usage only recently, the concept that quality assurance requires both a structured program and an appraisal mechanism has often been advocated by pioneers in the field. Leonard Rosenfeld identifies Florence Nightingale as an early pioneer because of her work published in 1858 comparing the mortality in the British army during the Crimean War with that of civilian populations. See Rosenfeld, *Standards for Assessing Quality of Care* in U.S. DEPT OF HEALTH, EDUCATION & WELFARE, *QUALITY ASSURANCE OF MEDICAL CARE* 10 (1973) [hereinafter cited as Rosenfeld]. In 1914, E.A. Codman, considered the father of the medical audit (the

existing methods of medical audit into three categories, "statistical," "scoring," and "scientific."¹² Lembcke's three categories are not exclusive, but instead each marks a point along a continuum of methods of review. The statistical method, apparently first used about 1920, involves the compilation and comparison of data designed to reflect the process of care, such as population characteristics, hospital size, length-of-stay in the hospital, the number and kind of procedures performed, and other indices of care. In the early 1950's, the Commission on Professional and Hospital Activities (CPHA) was formed,¹³ and today, with the aid of computers, processes, displays, and summarizes large masses of data that are relevant to the appraisal and control of medical care. Over one thousand hospitals currently subscribe to the services offered by CPHA, such as the Professional Activity Survey, the Medical Audit Program, and Length of Stay Package, which supply statistical measures of hospital and physician performance.

The problem with relying solely on the statistical method for quality assurance is that statistics merely describe and compare results. Furthermore, the earlier efforts of the CPHA emphasized institutional performance rather than the performance of the individual physician.¹⁴ Statistical findings do not of themselves suggest modes of action because there is no comparative absolute standard. A related criticism by Lembcke is that a statistical method does not significantly rely upon, or contribute to, a theory of cause and effect.¹⁵

The scoring method of medical audit was developed and refined by Wesley Eisele, who reviewed individual patient records by focusing on the procedures employed by the physician.¹⁶ The audit compared the proce-

process of review of medical care), observed that the proper objective of medical auditing was the end result; by this he meant whether the diagnosis or treatment produced the maximum cure or improvement that could be expected and whether the result was beneficial. See Codman, *The Product of a Hospital*, 18 SURGERY, GYNECOLOGY & OBSTETRICS 491 (1914). In 1918, the American College of Surgeons launched a system of hospital inspection, which was initially based on Codman's "accounting" or "end result" system. But a number of factors (see Rosenfeld, *supra*, at 10) limited the efforts of the college to establish standards of organization, procedures, and facilities, rather than examining end results. This approach was apparently based on the assumption, ingrained in current licensing statutes, that given adequate facilities, effective organization, and an efficient review system, good care will follow. Although experience has shown that these methods alone are not sufficient to ensure satisfactory results of care, [see INTERSTUDY, *supra* note 10, at 29] it is nevertheless true that the systematic reviews conducted by the American College of Surgeons were a significant factor in improving the quality of in-hospital care. See Rosenfeld, *supra*, at 10.

12. See Lembcke, *supra* note 9.

13. *Id.* at 68.

14. See Donabedian, *supra* note 8, at 22.

15. Lembcke, *A Scientific Method for Medical Auditing* (Part II), 33 HOSPITALS 65 (July 1, 1959).

16. See Eisele, *Methods of Evaluating Medical Care in Hospitals*, 53 ROCKY MT. MED. J. 1117 (1956).

dures against predetermined criteria. While this method appeared to improve the medical record and the quality of care, it had two major weaknesses: the criteria employed were subjective, often determined by individual hospitals, and it measured success in terms of compliance with procedures rather than by reference to achievement of "end results."

The development of the concepts employed in the statistical and scoring methods (*i.e.*, data-gathering and the comparison of cases to criteria) provided a foundation for the construction of more refined procedures of quality assessment. The early work of the American College of Surgeons, for example, offered a model for the original standards established by the Joint Commission on Accreditation of Hospitals (JCAH).¹⁷ Nevertheless, the early efforts of the JCAH suffered because there was no adequate methodology for measuring quality.¹⁸

Lembcke introduced a fresh approach. Drawing upon the concepts of the statistical and scoring methods, he improved them by relating the objective data produced by those methods to an articulated theory of cause and effect. The main features of Lembcke's "scientific" system were: classifying diagnoses into defined groups for comparison with predetermined criteria; verifying written statements in the clinical record; establishing the accuracy of laboratory reports; comparing the facts with the criteria; measuring the degree of compliance with the criteria against a standard degree of compliance; and computing incidence rates for the hospital's service community.¹⁹

Lembcke's system contained three important departures from previous audit systems. First, it recognized the need to include the patient in an audit before evaluating the outcome of his treatment. Before determining whether a patient was "successfully" treated for a specific disease, it must be established that the patient actually had the disease. Second, Lembcke's system allowed innovation in diagnosis and treatment because its recognition of degrees of compliance with the criteria provided flexibility. Finally, the system demonstrated an understanding that the quality of care can not be effectively evaluated solely through review of individual cases; the patterns of care must also be audited.²⁰ Applying this method, Lembcke developed criteria for his own use in external audits

17. See Rosenfeld, *supra* note 11, at 10.

18. Recently, the JCAH has shifted its emphasis. Rather than attempting to ensure conditions that would permit the delivery of high quality care, the focus is now on auditing and improving patient care. With the introduction of the Performance Evaluation Procedure (PEP), criteria for quality medical care are developed, medical practice is measured against these criteria, and the data is analyzed with a view toward identifying deficiencies and taking corrective action. See JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, THE PEP PRIMER (1974). These same general steps are part of the Medical Care Evaluation (MCE) study, which is an important part of the PSRO review system. See text accompanying notes 92-97 *infra*.

19. Lembcke, *A Scientific Method for Medical Auditing* (Part II), 33 HOSPITALS 65 (July 1, 1959).

20. *Id.*

that he performed, at the invitation of hospitals, to determine whether certain medical procedures were justified. A further refinement of his system, a modification of which PSRO utilizes, was developed by Beverly Payne.²¹ The Payne criteria differ from those of Lembcke in that they are developed by and agreed upon by the medical staff of the hospital, and the audit is internal, not external.²² An internal audit is performed by the hospital staff themselves rather than by outside consultants.

Thus, in the last quarter century methods of quality assessment have become more "scientific"; the original principles of structured review based on predetermined criteria have been extended, refined and modified, and actual audits demonstrate that these techniques are practical and effective. This scientific method is superior to the traditional method of record review, in which the medical staff examine haphazardly selected charts, because it more accurately reflects the whole range of care provided in an institution. The traditional method suffers from two serious flaws: it relies on the implicit and subjective clinical judgments of the individual reviewer, and it does not disclose patterns of improper care that might be corrected. The review offered by PSRO, the JCAH, and other criteria-based systems remedy those deficiencies.

B. *Inputs, Processes, and Outcomes*

As the medical audit and other mechanisms of quality assessment became more "scientific," medical care came to be categorized in terms of points along a continuum. Previous methods of medical audit focused on certain isolated segments of the process of care.²³ In 1966, however, Avedis Donabedian identified the three major approaches to the overall evaluation of medical care: structure (synonymous with "input"), process, and outcome.²⁴ These three concepts, which form the basis of the modern medical audit, recognize that medical care is not a single event but occurs over a period of time. Input, the first stage, refers to the structure within which care is provided.²⁵ It encompasses the personnel, environment, and instrumentalities that contribute to the provision of care. The concept of input is not limited to the physical aspects of facilities and equipment, but includes the administrative organization and the qualifications of health professionals. Donabedian observes that considerations of input as an indicator of quality involve two assumptions: that it is possible to identify

21. See Payne, *Continued Evolution of a System of Medical Care Appraisal*, 201 J.A.M.A. 536 (1967); text accompanying notes 85-98 *infra*.

22. See Donabedian, *supra* note 8, at 27-28.

23. For example, Codman looked primarily at "end results" (see note 11 *supra*) and the American College of Surgeons emphasized the structure in which care was provided (see note 17 and accompanying text *supra*).

24. See Donabedian, *supra* note 8, at 14-41.

25. *Id.* at 2. See also Carlson, *Health Manpower Licensing and Emerging Institutional Responsibility for the Quality of Care*, 35 LAW & CONTEMP. PROB. 849, 860-61 (1970).

what is "good" in terms of staff, facilities, and organization, and that better care is more likely when better qualified staff, improved physical facilities, and sounder fiscal and administrative organization are employed.²⁶ He further emphasizes, as have several others,²⁷ that input should not be equated with quality; the concept of input merely reflects the expectation that good inputs are more likely to produce good quality care.

Evaluation of process is the second approach to the assessment of medical care described by Donabedian. The process of medical care encompasses the activities of health personnel in the management of patients²⁸ through diagnosis and treatment. Reliance upon process as an indicator of the quality of care also entails two assumptions: that medical care is useful in maintaining and promoting health, and that particular elements of care are known to be related directly to certain health outcomes.²⁹ Furthermore, if the evaluation of process is to produce useful results, there must be a major working assumption that diagnosis and treatment make a difference in how patients feel. In addition, when criteria are developed for the evaluation of process, there is an assumption that each criterion relating to an element of care has some bearing on patient results. For example, one criterion for the evaluation of the process of diagnosis of appendicitis might be an "abdominal examination." In such a case, the implicit assumption is that the performance of an abdominal examination on a patient suspected of having appendicitis makes a difference in the patient's "end result."

Finally, the concept of outcome of medical care involves such diverse items as morbidity, mortality, work status of the patient, and patient satisfaction. Focus on the outcome of care necessarily involves the patient and reflects a primary concern for health status and the achievement of health objectives.

Input, process, and outcome are interrelated and each corresponds to a segment along the medical care continuum. Any method that seeks to evaluate care, or control the quality of care must incorporate these elements. A method that concentrates on only one component cannot determine whether quality care is being administered or whether quality care will continue.

26. See Donabedian, *supra* note 8, at 2-3.

27. See, e.g., INTERSTUDY, *supra* note 10, at 30-31; Cohen, *State Licensing Boards and Quality Assurance: A New Approach to an Old Problem*, in U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, *QUALITY ASSURANCE OF MEDICAL CARE* 49-55 (1973); U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, *REPORT ON LICENSURE AND RELATED HEALTH PERSONNEL CREDENTIALING* 5-6 (1971); Carlson, *Health Manpower Licensing and Emerging Institutional Responsibility for the Quality of Care*, 35 LAW & CONTEMP. PROB. 849, 859-61 (1970).

28. See Carlson, *Health Manpower Licensing and Emerging Institutional Responsibility for the Quality of Care*, 35 LAW & CONTEMP. PROB. 849, 859-62 (1970); Donabedian, *supra* note 8, at 3.

29. See Donabedian, *supra* note 8, at 3.

While methods for *assessing* input, process, and outcome were being developed and slowly introduced within the medical profession, measures intended to *control* the quality of care were also evolving.³⁰ As with assessment measures, these control devices focused on the input segment of the medical care continuum³¹ in such areas as personnel, facilities, equipment, and organization. Few controls have been developed for the process or outcome areas.

The various input control measures include undergraduate and graduate school admission requirements, the education process, initial professional licensing, and specialty certification. With respect to facilities, the relevant factors include accreditation of schools and health care institutions, building codes, and public health standards. All these controls, most quite detailed, seek to assure that there are good inputs that will produce good patient outcomes.³²

An increasing number of critics suggest that the benefits of input regulation may have been overestimated.³³ Several studies disclose little correlation between such elements as length of training, board certification, hospital accreditation, or examination scores and quality of care.³⁴ Although historically input regulation was used because it was the only available methodology, regulation of input may also have been emphasized because it focused more on the provider of care than on the consumer. While the original purpose of licensing was to protect the public from dishonest and incompetent practitioners, it also allowed the profession to decide who will practice.³⁵ Professional educational standards have the potential to produce the same effect.³⁶ Yet the consumer is primarily

30. Assessing quality and attempting to control it are different problems. The former involves measurement and analysis; the latter involves dictating standards. There is, of course, some interrelationship between the two — goal assessment may involve the identification and correction of deficiencies. In addition, control measures should reflect assessment findings that changes are indicated and that the dictated standards are appropriate.

31. See INTERSTUDY, *supra* note 10, at 28–31; Carlson, *Health Manpower Licensing and Emerging Institutional Responsibility for the Quality of Care*, 35 LAW & CONTEMP. PROB. 849, 860–61 (1970).

32. See Donabedian, *supra* note 8, at 2.

33. See, e.g., Carlson, *Health Manpower Licensing and Emerging Institutional Responsibility for the Quality of Care*, 35 LAW & CONTEMP. PROB. 849, 860 (1970); Lave & Lave, *Medical Care and Its Delivery: An Economic Appraisal*, 35 LAW & CONTEMP. PROB. 252 (1970).

34. See, e.g., INTERSTUDY, *supra* note 10, at 29 (“The point is that while some correlation exists between input regulation and outcomes performance, it is not sufficient to prevent a high degree of variability in quality of care and perhaps even unsatisfactory overall levels of care.”)

35. See U.S. DEP’T OF HEALTH, EDUCATION & WELFARE, REPORT ON LICENSURE AND RELATED HEALTH PERSONNEL CREDENTIALING 2 (1971).

36. Kessel, *The A.M.A. and the Supply of Physicians*, 35 LAW & CONTEMP. PROB. 267, 268, 282 (1970). See also Cohen, *Regulatory Politics and American Medicine*, 19 AM. BEHAVIORAL SCIENTIST 122 (1975).

concerned with the outcome, less with the process of care, and still less with the input. Given this patient attitude it is ironic that quality assurance programs have stressed the input segment of the spectrum.

Control measures directed at the process of care are fewer and less formal than input controls. The current control techniques are peer review,³⁷ utilization review,³⁸ continuing education requirements,³⁹ tissue committees, license revocation, suspension, and other sanctions. But the present and past forms of review lack both predetermined standards, which would allow comparisons of care, and a structure, which would enable objective review.⁴⁰

Several observers have suggested that there are no quality assurance mechanisms concerned with the outcome segment of the medical care continuum. Most agree that the assessment of outcome should reflect the condition of patients at the conclusion of care and that standards for outcomes should reflect general patterns of care rather than individual cases.⁴¹ The following section will examine whether malpractice litigation actually serves as a control over the outcome of care.

C. *The Malpractice System as a Quality Assurance Mechanism*

The medical malpractice tort system serves three general functions: quality assurance, discipline, and compensation. Whether such a haphazard system can be efficient, just, or adequate in any of those capacities is questionable.⁴² Although the threat of litigation by a dissatisfied patient

37. See generally R. BROOK, *QUALITY OF CARE ASSESSMENT: A COMPARISON OF FIVE METHODS OF PEER REVIEW* (1973); Donabedian, *supra* note 8, at 1-2.

38. See, e.g., Nelson, *Relation Between Quality Assessment and Utilization Review in a Functioning PSRO*, 292 NEW ENGLAND J. MED. 671 (1975). See generally Jacobs & Christoffel, *The Rationale for Outcome Audit*, in JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, *THE PEP PRIMER* (Part III) 13-24 (1974).

Hospital-based utilization review is supposed to assure appropriate allocation of hospital resources. It seeks to determine whether a particular patient requires a particular unit of health service, be it an admission, a period of hospital stay, or a specified diagnostic or therapeutic procedure. Generally, utilization review must be accomplished concurrently rather than retrospectively as with audit — because once a unit is allocated it is then consumed, and the cost consequence is immediately realized.

Id. at 17.

39. Maryland, for example, by statute has empowered its Board of Medical Examiners to establish continuing education requirements as a condition of reregistration. MD. ANN. CODE art. 43, § 128(c) (Cum. Supp. 1976).

40. See Lembcke, *Medical Auditing by Scientific Methods*, 162 J.A.M.A. 646 (1956).

41. See, e.g., Jacobs & Christoffel, *The Rationale for Outcome Audit*, in JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, *THE PEP PRIMER* (Part III) 30-32 (1974).

42. See, e.g., Havighurst, "Medical Adversity Insurance" — *Has Its Time Come?*, 1975 DUKE L.J. 1233, 1234-35; O'Connell, *An Alternative to Abandoning Tort Lia-*

may influence the quality of medical care,⁴³ the extent and effectiveness of this deterrence are uncertain at best. Yet consumers perceive the malpractice system as an important means of quality assurance because there is no other course available to them. During the current malpractice crisis, the primary opponents to changing the malpractice system have been the representatives of the patient-consumer, the plaintiffs' bar.⁴⁴ Because the malpractice system is thought to offer quality control to the consumer, any alternative to the present scheme of patient compensation that fails to recognize the consumer's interest in quality would be inadequate.

Although the malpractice system can serve as a quality assurance mechanism, it is grossly inefficient in this capacity, for its primary mode of control is deterrence, the threat of a lawsuit in the event of malpractice. The system has not developed a review procedure that could routinely identify bad practice and effect changes. While malpractice liability purports to use a standard based on the due care exercised by others similarly situated, the standards of measurement are not always valid, and in some cases a court may substitute its independent judgment as to the proper standard of care.⁴⁵ The failure to identify bad outcomes in a systematic fashion, the absence of any procedure for changing the process to achieve outcomes, and the lack of any process designed to evaluate the effect of the system, all argue against the continued reliance on the medical malpractice tort system for quality control.

The malpractice system is also seen as a means to discipline health care providers, but it is equally deficient in this respect. In many states, the only sanction available to a licensing board against physicians who commit malpractice is revocation.⁴⁶ Understandably, the state boards are

bility: Elective No-Fault Insurance for Many Kinds of Injuries, 60 MINN. L. REV. 501, 501-20 (1976).

43. It is generally accepted that the malpractice system does not provide a very good control on the outcome of patient care. See Jacobs & Christoffel, *The Rationale for Outcome Audit*, in JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, THE PEP PRIMER (Part III) 10 (1974). See generally Brook, Brutoco & Williams, *The Relationship Between Medical Malpractice and Quality of Care*, 1975 DUKE L.J. 1197.

44. See remarks of Robert Cartwright, President of the Association of Trial Lawyers of America, in SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94th Cong., 1st Sess., NATIONAL CONFERENCE ON MEDICAL MALPRACTICE 25-26 (Subcomm. Print 1975) (citing instances in which diligent trial lawyers, working under the contingency fee system, have been responsible for rooting out and bringing before the bar of justice many incompetent and negligent doctors).

45. See, e.g., *Helling v. Carey*, 83 Wash. 2d 514, 519 P.2d 981 (1974), noted in O'Hern, *Leading Cases*, 230 J.A.M.A. 1577 (1974); Bradford, *A Unique Decision*, J. LEG. MED. 52 (Sept./Oct. 1974).

46. For a discussion of the deficiencies of licensing as a means of quality control, see U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE 51-52 (1973) [hereinafter cited as HEW REPORT]; Brook, Brutoco & Williams, *The Relationship Between Medical Malpractice and Quality of Care*, 1975 DUKE L.J. 1197, 1215-17.

reluctant to impose such Draconian measures, although recently state legislatures and physician groups have expanded the range of disciplinary measures.⁴⁷ Another problem is that most state boards lack the power to discipline solely on the basis of incompetent practice.⁴⁸ Nevertheless, to some the malpractice system appears to close this gap in the disciplinary process because it offers a means of disciplining the incompetent physician.

Malpractice liability also functions inefficiently as a system of patient compensation. It is estimated that only sixteen percent of the professional liability premium dollar eventually reaches the injured plaintiff.⁴⁹ This figure is somewhat misleading since the real purpose of professional liability insurance is not to compensate patients but to defend physicians against claims. Nevertheless, it indicates the inordinate administrative costs associated with the malpractice system and the need to develop other compensation schemes that minimize these costs.

Thus, aside from its historical background in tort law, the malpractice system continues because it is the only game in town. It provides the only control on the outcome of medical care; it offers one method of physician discipline, and it serves as the primary mechanism of patient compensation. While it is inefficient, unjust, or inadequate in performing these functions, it continues to operate because there are no alternatives and because it is the only current process that considers the interests of the consumer. Any alternative to the malpractice system must therefore address those interests.

II. PSRO

A. *An Overview*

Professional Standards Review Organizations involve a system of review operated at the local level by practicing physicians. These physicians review the medical necessity and appropriateness of care that is reimbursed under federal programs. The PSRO seeks to assure that the medical

47. See A LEGISLATOR'S GUIDE TO THE MEDICAL MALPRACTICE ISSUE 7 (D. Warren & R. Merritt eds. 1976).

48. See HEW REPORT, *supra* note 46, at 52.

49. CENTER FOR THE STUDY OF DEMOCRATIC INSTITUTIONS, MEDICAL MALPRACTICE: A DISCUSSION OF ALTERNATIVE COMPENSATION AND QUALITY CONTROL SYSTEMS 5 (D. McDonald ed. 1971). For other estimates, see O'Connell, *An Alternative to Abandoning Tort Liability: Elective No-Fault Insurance for Many Kinds of Injuries*, 60 MINN. L. REV. 501, 506-12 (1976) (estimating that the malpractice tort system returns 28 cents of the premium dollar to injured patients, of which only 12.5 cents reimburses the patient for losses not otherwise compensated); STAFF OF HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94th Cong., 1st Sess., AN OVERVIEW OF MEDICAL MALPRACTICE 5 (Comm. Print 1975) ["The amount of each premium dollar actually awarded to the patient or his legal representative may range from 16 to 38 cents, depending upon which estimate is accepted." (remarks of Representative Hastings)]; HEW REPORT, *supra* note 46, at 33-35.

services meet professionally recognized standards of care. In the case of inpatient care, the local PSRO must also determine whether the setting (*i.e.*, acute care hospital, nursing home, etc.) of that care is appropriate. The 1972 Amendments to the Social Security Act⁵⁰ adopted this concept. The legislation was based on the concept that physicians are the most appropriate judges of the quality of medical services and that peer review at the local level is the best method for assuring the appropriate use of health facilities. The local PSRO provides the structure for the operation of this procedure.

The legislation required the Secretary of the Department of Health, Education, and Welfare to designate PSRO geographic areas and then enter into agreements with qualified organizations in each area.⁵¹ Prior to January 1, 1978, only a nonprofit professional association representing a substantial portion of the practicing physicians in the area can qualify as a PSRO.⁵² After that date, if no physician organization has applied, the Secretary can designate any other group that has the competence to perform PSRO functions.⁵³

Initially, review will be limited to institutions such as short-term acute care hospitals and skilled nursing facilities, although the legislation does not prohibit the review of ambulatory care.⁵⁴ PSROs are to delegate the duties of review to local institutions if their internal review procedures are found to be effective.⁵⁵ The PSRO must review the physician and patient profiles of the institutions and apply regional norms of care in the review process.⁵⁶ Fiscal intermediaries (those public or private agencies which, by agreement with HEW, make the payments reimbursing providers under Medicare)⁵⁷ must accept a PSRO determination regarding the necessity of care in reimbursing Medicare claims.⁵⁸

On March 13, 1974, the Secretary designated 203 geographic areas within which PSRO's would be established.⁵⁹ Qualified physician organizations applied for and were awarded contracts by HEW for the initial planning phase of review activities. Local PSROs have subsequently "graduated" to conditional status, in which the review activities and capacity are developed and expanded. If at the end of the conditional period the Secretary finds that the PSRO has satisfactorily demonstrated its effectiveness, it will become fully qualified and operational.⁶⁰ By July

50. 42 U.S.C. §§ 1320c-1 to -19 (1974).

51. 42 U.S.C. § 1320c-1(a) (1974).

52. 42 U.S.C. §§ 1320c-1(b)(1), (c)(1) (1974), *as amended* Pub. L. 94-182, § 108 (Dec. 31, 1975).

53. *Id.*

54. 42 U.S.C. § 1320c-4(g) (1974).

55. 42 U.S.C. § 1320c-4(e)(1) (1974).

56. 42 U.S.C. §§ 1320c-4(a)(4), 1320c-5(a) (1974).

57. *See* 42 U.S.C. § 1395h (1974).

58. 42 U.S.C. §§ 1320c-4(a)(1), 1320c-7 (1974).

59. *See* 39 Fed. Reg. 10204 (1974).

60. 42 U.S.C. § 1320c-3(b) (1974).

1, 1976, there were 87 local PSROs in conditional status and 33 areas in the planning phase, a total of 120 areas representing 46 states, the District of Columbia, and Puerto Rico.

The PSRO program structures data collection, processing, and reporting so as to assure maximum efficiency, economy, and coordination in all data-gathering efforts as well as compatibility of data across different geographic areas.⁶¹ Data generated from the Medicare and Medicaid programs is to be utilized to the greatest extent possible. The law requires that the information remain confidential and that disclosure be limited to the amount necessary to perform PSRO functions while protecting the rights of patients, practitioners, and other providers.⁶²

The statute grants review and a hearing in the event of an adverse PSRO determination⁶³ and also provides for the imposition of sanctions against practitioners and institutional providers.⁶⁴ While regulations have not yet been promulgated to elaborate those provisions of the statute, the Secretary may terminate or suspend Medicare or Medicaid reimbursement for services by a provider who is responsible for gross or continued overutilization of services or for inadequate quality of service. In the alternative, the Secretary may require the offending person to reimburse the government money already received up to five thousand dollars for medically unnecessary services.⁶⁵

The local PSRO is the most important unit in the structure of the PSRO program. In states with three or more PSROs, Statewide Professional Standards Review Councils, which include representation of non-physicians, are to be established.⁶⁶ The Statewide Council serves several functions: the coordination of PSRO activities within a state, the dissemination of information, and review of PSRO performance.

The National Professional Standards Review Council, the third major component of the PSRO structure, consists of physicians who are recognized authorities in the review of medical care.⁶⁷ It currently has eleven members appointed by the Secretary. Its primary function is to collect data and other information and disseminate it to PSROs, particularly information relating to the development and application of norms, standards, and criteria for care. It also serves as a policy advisory group to the Secretary.

PSRO, with certain exceptions, is not a hierarchical system. Each component (the local PSRO, the Statewide Councils, and the National Council) performs distinct functions. The local PSRO is responsible for performing review, the Statewide Council coordinates PSRO activities,

61. See U.S. DEPT OF HEALTH, EDUCATION & WELFARE, PSRO PROGRAM MANUAL § 107 (1974) [hereinafter cited as PSRO PROGRAM MANUAL].

62. 42 U.S.C. § 1320c-15 (1974).

63. 42 U.S.C. § 1320c-8 (1974).

64. 42 U.S.C. § 1320c-9(b) (1)-(2) (1974).

65. 42 U.S.C. § 1320c-9(b) (3) (1974).

66. 42 U.S.C. § 1320c-11 (1974).

67. 42 U.S.C. §§ 1320c-12(a), (b) (1974).

and the National Council addresses general policy matters. Information is exchanged between the levels, but neither the Statewide nor the National Council exercises continuous supervision over local PSRO activities. There are two primary exceptions to this policy of local autonomy. Individuals who disagree with a local PSRO determination may appeal to a Statewide Council,⁶⁸ and the National Council has the responsibility to determine whether locally developed norms and standards differ significantly from regional ones.⁶⁹

B. Norms, Standards, and Criteria

The formulation of the norms, standards, and criteria by which PSROs review medical care has encountered criticism and hindered understanding of the program.⁷⁰ Critics argue that since there is little agreement about the efficacy of various diagnostic procedures and therapeutic interventions, there is no basis for standard-setting. Furthermore, it is feared that the establishment of standards may stagnate medical practice and encourage "cookbook medicine." On the other hand, the very process of standard-setting may prove highly educational.⁷¹ A brief explanation of the terms employed and their meaning may be informative.

The PSRO enabling legislation required local PSROs to apply "professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions."⁷² But there was no clear definition of the term "norms," nor was there any generally accepted meaning of the terms "standards" and "criteria." Consequently, the American Medical Association's Advisory Committee on PSRO and the National PSR Council developed the following definitions:⁷³

Norms: Medical care appraisal norms are numerical or statistical measures of usual observed performance.

Standards: Standards are professionally developed expressions of the range of acceptable variation from a norm or criterion.

Criteria: Medical care criteria are predetermined elements against which aspects of the quality of a medical service may be compared.

68. 42 U.S.C. §§ 1320c-8(b), (c) (1974).

69. 42 U.S.C. §§ 1320c-5(a), (c) (1) (1974).

70. See, e.g., Boikess & Winsten, *Can PSRO Procedures be Both Fair and Workable?*, 24 CATH. U.L. REV. 407, 434-38 (1975); Fifer & Aldrich, *The Tyranny of Standards*, 231 J.A.M.A. 709 (1972); Springer, *PSROs: Implications for Legal Liability*, THE HOSPITAL MEDICAL STAFF 1 (Jan. 1975). See also *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125 (N.D. Ill. 1975) (plaintiffs sought to enjoin HEW from implementing the Professional Standards Review Law primarily on the fifth amendment grounds of overbreadth and vagueness).

71. See Jessee, Munier, Fielding & Goran, *PSRO: An Educational Force for Improving Quality of Care*, 292 NEW ENGLAND J. MED. 668 (1975).

72. 42 U.S.C. § 1320c-5(a) (1974).

73. See PSRO PROGRAM MANUAL, *supra* note 61, at § 709; note 75 *infra*.

Thus, a norm is a number, statistic, or statement that is capable of verification. For example, a norm for the length of stay for all patients with the diagnosis of appendicitis might be five days in a particular PSRO area or hospital. If a survey of hospitals in a PSRO area reveals that the average hospital length of stay for all patients with a diagnosis of appendicitis is five days, then five days would be the norm for the area. The identification of a norm does not disclose whether a situation is good or bad, simply that it exists. Thus, norms are solely descriptive.

A criterion, on the other hand, is developed through survey, literature examination, or professional experience. It suggests what *should be* rather than what is. For example, through an examination of the literature and a consideration of professional expertise, a PSRO might set a criterion for length of stay in appendicitis cases at four days.

Finally, a standard indicates an acceptable screening variation from a norm or, most likely, a criterion. For example, the PSRO might decide that although four days is the optimum length of stay for a patient with appendicitis, the disease is so variable that a standard of three to seven days would be acceptable. Cases falling within the standard would "pass" screening; cases outside the standard would be subjected to peer review.

Norms, criteria, and standards are to be used at each level of PSRO review. The PSRO Program Manual contemplates their application in the initial screening of cases to select those that require more detailed review.⁷⁴ In-depth review is conducted by peers through a combination of more detailed norms, criteria, and standards. These peers also assess the patient's individual clinical and social situation as well as the resources of the institution in which care is provided.⁷⁵

The purpose of screening is to make the review process efficient by using nonphysicians, who apply criteria that pertain to the proper diagnosis or treatment of the patient, to identify instances of health care that fall outside predetermined standards. In applying those standards, however, some competent practitioners may be subjected to further review because the particular circumstances of the case involved do not meet the criteria. For example, a PSRO may have set criteria concerning the

74. *Id.*

75. *Id.* The PSRO legislation requires that local PSROs use information supplied to them by the National PSR Council as a principal point of review. 42 U.S.C. §§ 1320c-5(a), (c)(1)-(2) (1974). In partial fulfillment of that continuing responsibility, the National Council, through contract between the American Medical Association and the Department of Health, Education and Welfare, has provided model screening criteria to assist PSROs. See AM. MEDICAL ASS'N, SAMPLE CRITERIA FOR SHORT-STAY HOSPITAL REVIEW (1976). The AMA contracts, performed in conjunction with thirty-five medical specialty societies, were intended to establish model criteria for screening the appropriateness, necessity, and quality of medical service in acute care short-stay general hospitals. Screening criteria were developed for those diagnoses that account for 75 percent of hospitalizations within each specialty. The criteria, now in final form, have been distributed to all local medical societies, hospitals, and PSROs in the country.

length of hospital stay for a patient with a heart attack, and a particular case may be identified through screening as exceeding that length of stay. That case is then referred to peer review, which might determine that the additional length of stay was justified because of individual complications that were not considered when the criteria were developed.

The screening criteria provide an effective review mechanism by selecting the small number of cases for which peer review is appropriate.⁷⁶ They reduce physician review time since physicians examine only those cases in which there is a greater potential that a problem exists. Screening criteria do not prescribe rigid standards of quality nor determine what services shall be paid for. They do not preclude physician innovation, nor do they provide a complete review system that analyzes and evaluates the quality of care.⁷⁷ It is the subsequent peer review and retrospective in-depth study of the specific problems that require more comprehensive criteria.

The AMA model criteria⁷⁸ form the foundation for the development of local PSRO standards. Over time, norms, criteria, and standards should be developed for each major diagnosis, health problem, or procedure that will be reviewed. Since the completion of this venture will take many years, the early focus will be on high priority situations identified by the local PSRO because of the frequency of the disease process, the degree of health improvement possible, and the degree to which inappropriate utilization or substandard quality is evident.⁷⁹

To alleviate the fear that the establishment of standards will stagnate the development of medicine, the statute requires local PSROs to provide a plan for periodic review and modification of the standards.⁸⁰ Although this review process alone does not guarantee current standards, it is hoped that local physician organizations charged with the formulation of standards will be flexible and amenable to change.

One beneficial aspect of the PSRO structure is the educational potential. If PSROs are to set standards for the evaluation of the quality of care, there must be some determination that information used to construct the standards and criteria is valid. The history of standard setting, though sparse, suggests that there is substantial disagreement within the

76. AM. MEDICAL ASS'N, SAMPLE CRITERIA FOR SHORT-STAY HOSPITAL REVIEW iv-vi (1976).

77. *Id.* Examples of screening criteria categories are justification and reason for admission, length of stay, validation of diagnosis, critical diagnostic and treatment services, discharge status, and complications. *See id.* at 4-11. With a diagnosis of appendicitis, for instance, the critical therapeutic service would be appendectomy or drainage of abscess, and a factor in the discharge status would be that the patient was afebrile. If the criteria are not met, the patient record would be passed on for peer review.

78. *See* note 75 *supra*.

79. PSRO PROGRAM MANUAL, *supra* note 61, at § 709.13.

80. 42 U.S.C. § 1320c-5(c) (1) (1974).

medical profession on the nature of valid medical information.⁸¹ Little is known about the actual value of many diagnostic procedures and therapeutic interventions.⁸² In fact, some studies indicate that much of the data used in clinical practice may simply be wrong.⁸³ This uncertainty means that many of the conclusions expressed in scientific papers, upon which many practitioners rely, cannot be supported with statistics.⁸⁴ The problem of uncertainty suggests two considerations with respect to PSROs. First, criteria setting must necessarily be general, and standards should allow wide variation in those general areas. Second, the determination that a specific piece of information is invalid indicates that further research is desirable.

Thus, PSRO promotes medical education by encouraging practitioners to ask questions about the nature of curable diseases, the success of present medical care process, the availability of methods of diagnosis and treatment, and the validity of the information available concerning those methods. This inquiry does not force the patterns of practice into "cookbook medicine" any more than it requires that research be done. The questioning by the local PSRO in its standard-setting process may open a dialogue between the researcher and the practitioner. The process of inquiry informs the researcher about the areas where practitioners have difficulty, and it also transfers valid information back to the practitioner.

C. *The Mechanism of Review*

When the PSRO legislation was enacted, there was little practical experience with scientific review that emphasized patient outcomes; most systems concentrated on the input stage of health care delivery. But the previous systems (*e.g.*, scoring, statistical, and scientific) provided the basic elements with which to develop an effective methodology for examining both the medical care process and, more importantly, its outcome.⁸⁵ Furthermore, with the advent of group practices, health maintenance organizations, specialization, and the increasing responsibility of institutions for the quality of medical care they provide, there is less of the

81. See Emlet, Williamson, Casey, Davis, Dittmer, Flagle & Miller, *ALTERNATIVE METHODS FOR ESTIMATING HEALTH-CARE BENEFITS AND REQUIRED RESOURCES 2* (Analytic Services, Nov. 30, 1971).

82. *Id.*

83. See, *e.g.*, *id.*; Williamson, *Evaluating Quality of Patient Care: A Strategy Relating Outcome and Process Assessment*, 218 J.A.M.A. 564 (1971); Williamson, Alexander & Miller, *Priorities in Patient-Care Research and Continuing Medical Education*, 204 J.A.M.A. 303 (1968); Williamson & van Nieuwenhuijzen, *Health Benefit Analysis: An Application in Industrial Absenteeism*, 16 J. OCCUP. MED. 220 (1974).

84. See, *e.g.*, Feinstein, *A Survey of the Statistical Procedures in General Medical Journals*, 15 CLIN. PHARM. & THERAP. 97 (1973); Schor & Karten, *Statistical Evaluation of Medical Journal Manuscripts*, 195 J.A.M.A. 1123 (1966).

85. See Williamson, *Evaluating Quality of Patient Care: A Strategy Relating Outcome and Process Assessment*, 218 J.A.M.A. 564 (1971).

fragmentation that once characterized the practice of medicine when it was dominated by single practitioners.⁸⁶ The growth of interrelated responsibility for care has exposed more of the practice of medicine to public view and this exposure makes it easier to evaluate the various patterns of health care delivery.

PSRO review integrates three separate review mechanisms: concurrent review, which involves admission certification and continued stay review; medical care evaluation studies; and institutional provider, practitioner, and patient profiles.⁸⁷ The purpose of the concurrent review system is to assure that hospital admissions are necessary, that length of hospital stays are appropriate and that patients are discharged at the proper time.⁸⁸ Through the first component of concurrent review, admission certification, the medical necessity of admission is examined and an initial length of stay established. In practice, a trained nonphysician will compare the admitting diagnosis with PSRO-developed criteria for admission. If the patient were admitted with the diagnosis of appendicitis, then, under the AMA criteria,⁸⁹ either a suspicion of acute appendicitis or a previously scheduled operation for the disease would justify admission. After admission has been approved, an initial length of stay, based on PSRO norms, would be assigned.⁹⁰ Continued stay review would complete concurrent review, inquiring whether critical diagnostic and treatment criteria were satisfied by the patient's care and whether the patient outcome was appropriate.⁹¹ If the initial reviewer of the record discovers a conflict with the screening criterion, the individual record would be forwarded to the physician reviewer for further scrutiny. But an inconsistency with screening criterion does not necessarily mean denial of reimbursement.

The purpose of medical care evaluation (MCE) studies, the second element of PSRO review, is to improve quality through systematic study. This process is designed to identify deficiencies in the quality of health care and in the organization and administration of its delivery, to correct such deficiencies through education and administrative change, and to reassess performance periodically to assure that improvements have been maintained.⁹² MCEs also help to determine the effectiveness of concurrent review and assist in validating norms, criteria, and standards.

86. See INTERSTUDY, *supra* note 10, at 35-39.

87. PSRO PROGRAM MANUAL, *supra* note 61, at § 701.

88. *Id.*

89. AM. MEDICAL ASS'N, SAMPLE CRITERIA FOR SHORT-STAY HOSPITAL REVIEW 67 (1976); see note 75 *supra*.

90. PSRO PROGRAM MANUAL, *supra* note 61, at §§ 705 - 705.26.

91. *Id.* at § 705.21.

92. *Id.* at § 705.31.

93. Director, Bureau of Quality Assurance, Health Services Administration, Dep't of Health, Education & Welfare, Draft Transmittal — BQA Policy on Medical Care Evaluation (MCE) Studies (HEW memorandum, Aug. 22, 1976).

An MCE consists of seven steps.⁹³ The first is priority setting, which involves the identification of what problem, diagnosis, or procedure should be subject to study.⁹⁴ The second step is criteria setting. MCE criteria would contain the same elements (admission justification, diagnostic services, etc.) as screening criteria,⁹⁵ but would be more comprehensive and would be designed to evaluate patterns of care rather than screening individual admissions.⁹⁶ The last five steps in the MCE are the audit or review process, problem definition, problem etiology determination and identification of the failure in process leading to a poor outcome, change in process with a view to bettering the outcome, and reaudit (reevaluation following change in process).⁹⁷

An example will illustrate the MCE process. If priority setting identified hypertension as a possible MCE subject, the PSRO would develop criteria for hypertension. Data developed from the audit review process might reveal a wide disparity in incidence within the PSRO of myocardial infarction, stroke, and renal disease. Poor outcomes being part of the problem identification step in the MCE, further evaluation might reveal a correlation between low incidence of complications and an active post-hospitalization patient education program. In that case, the MCE would have served a useful purpose in providing the data on the beneficial effect of patient education that changed the process of care.

The third major component of PSRO review is profile analysis, which attempts to monitor the effectiveness of the other components of the review system and to determine their optimal use.⁹⁸ In addition, by distinguishing between normal and consistently aberrant practice patterns, profile analysis allows the PSRO or hospital to modify their concurrent review programs to focus on defined problems. Profile analysis may further involve a comparison of physicians' practices and of hospitals' health services delivery in such gross areas of patient outcomes as mortality and morbidity, and in areas of health services utilization such as average length of stay and inpatient cost. Where such comparisons indicate significant variation, the PSRO may choose to institute an MCE or to examine its concurrent review criteria.

94. Although particular methods of priority setting will be left up to local PSROs, guidelines that relate to patient benefit have been suggested. Diagnoses which would be appropriate for early MCEs might have the following characteristics: a high frequency of occurrence, a high health system impact, a high level of agreement within the medical profession regarding the appropriate process of care, clearly identifiable outcomes, complications both identifiable and due to the medical care process, a natural history shown to vary with treatment, increased morbidity if services are underutilized, and amenability to data-gathering. See Goran, Roberts, Kellogg, Fielding & Jessee, *The PSRO Hospital Review System*, 13 MEDICAL CARE 1, 19 (Apr. 1975 Supp.).

95. See text accompanying notes 77-78 *supra*.

96. See PSRO PROGRAM MANUAL, *supra* note 61, at § 705.35.

97. Goran, Roberts, Kellogg, Fielding & Jessee, *The PSRO Hospital Review System*, 13 MEDICAL CARE 1, 19-22 (Apr. 1975 Supp.).

98. PSRO PROGRAM MANUAL, *supra* note 61, at § 701.

III. CONCLUSION

The malpractice liability system is inefficient as a means of compensating injured patients, disciplining negligent health care providers, and assuring the public that they will receive quality health care. Although it may encourage defensive medicine (*i.e.*, providing more care than may be necessary in order to avoid a malpractice suit) or force physicians to change a prevailing standard of care in response to losing a malpractice suit, these rather uncertain and haphazard benefits have not significantly altered the structure of health care so as to assure consumers that they receive quality medical care. Nevertheless, because the malpractice system is the only means through which the consumer can express his dissatisfaction with negligently administered medical care and hope to obtain relief for his injuries, the public and the plaintiffs' bar perceive the system as a quality assurance mechanism.

This article has attempted to present a coherent description of the practice and theory of PSRO. If the program successfully assures the public of better quality medical care, then some of the problems now caused by the present medical malpractice liability system may be alleviated. Since PSRO applies objective standards within an organization that systematically examines patterns of practice, it can identify poor outcomes, locate the associated failure of practice, and change the practice so as to change the outcome. In this fashion it is able to complete the feedback loop which the malpractice system leaves open. PSRO is not, however, a complete alternative to the malpractice system. It neither compensates injured patients nor disciplines negligent doctors. Nevertheless, by supplying a method of quality control that is more effective than the malpractice system, PSRO may encourage the development of alternatives to malpractice liability in the areas of compensation and provider discipline.